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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/749,513

01/02/2004

John Nash

0119/0029

8687

21395 7590 02/20/2009

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

02/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/749,513 | Applicant(s) NASH ET AL. | |
| | Examiner Danton DeMille | Art Unit 3771 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 12 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 21-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION**Status of the Claims**

The examiner's amendment of 5 April 2008 has been withdrawn. The claims are as of the last amendment dated 18 December 2007. Claims 11, 12 and 21-33 are pending.

Election/Restrictions

Newly submitted claims 21-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: a method of making a face mask of plastic material is a distinct invention because the face mask can be made by a materially different process such as bonding.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-33 have withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

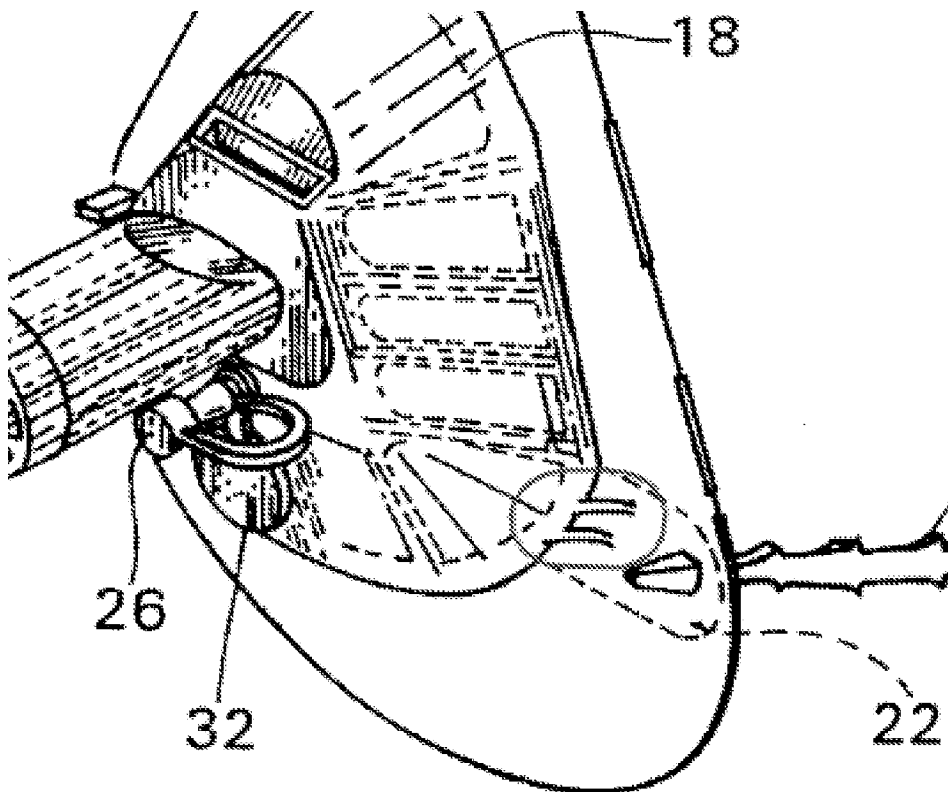
Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malis et al. in view of Fecteau et al.

Malis teaches, for example, a face mask of plastics material, column 3, lines 17-19, comprising a relatively soft canopy member 10, 18 having a peripheral sealing edge 12 adapted to provide a seal with the skin. The canopy member 10, 18 including a relatively rigid reinforcement member 44 in the form of a frame having a plurality of radially-extending arms as shown in figures 1 and 2. The reinforcement member 44 being moulded integrally with the canopy member, column 5, lines 19-22. The mask also include at least one gas port 14, 24, 30

by which gas can enter the mask. Figures 1 and 2 show the reinforcement member 44 has a plurality arms extending toward the edge of the mask on one side however, Malis appears silent regarding whether or not the opposite side of the mask also has the same arrangement of arms extending to the edge of the mask. It would be inherent that the mask is symmetrical and would have the same arrangement of reinforcement arms extending to the edge of the mask on the other side of the mask. If it is felt that this would not be inherent then it would have been obvious to modify Malis to include the same arrangement of reinforcement arms on the opposite side of the mask so that the mask would be structurally uniform. The arms of the reinforcement member 44 also terminate in lateral bars that extend substantially parallel to the edge of the mask all the way around the perimeter of the mask as shown in figures 1 and 2. There appears to be no positive structural difference between the mask of Malis and the claimed invention. The only difference between the claims and Malis is the method of how the reinforcement member was formed in the canopy member. Malis appears silent regarding whether or not the integral forming process is a dual-shot moulding process. It is not clear how much weight can be given this limitation since the claim is drawn to the apparatus and not the method because the determination of patentability in a product-by-process claim is based on the product itself, even though the claim may be limited and defined by the process. That is, the product in such a claim is unpatentable if it is the same as or obvious from the product of the prior art, even if the prior product was made by a different process. In *re Thorpe*, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985). A product-by-process limitation adds no patentable distinction to the claim, and is unpatentable if the claimed product is the same as a product of the prior art.

However, Fecteau is sited to teach the two shot moulding process is well known even in the art of forming masks. Fecteau teaches in column 3, lines 34-37, “the facepiece 22 and yoke 14 are integrally molded into a single element by a known process, such as by dual shot molding”. If it is felt the moulding process limitation further defines the claimed invention then it would have been obvious to one of ordinary skill in the art to modify Malis to form the canopy member 10, 18 and the reinforcement member 44 in a dual shot moulding process as taught by Fecteau as an obvious equivalent method of forming the mask that would produce the same resulting structure.

Regarding claim 12, Malis teaches a harness 16 arranged to extend around the head of the patient. The lateral bars would also appear to support a fastener 22 to which the harness 16 is attached as highlighted below. There are strengthening ribs that extend from the lateral bars to



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the fastener 22 to strengthen to fastener within the reinforcement member 44 within the canopy 10, 18 of the mask.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974.

The examiner can normally be reached on M-F from 8:30 to 6:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu, can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

20 February 2009

/Danton DeMille/

Danton DeMille
Primary Examiner
Art Unit 3771